

A User's Guide to Available EPA Information on Assessing Dietary (Food) Exposure to Pesticides

DRAFT December 22, 1998

EPA's Office of Pesticide Programs (OPP) regulates pesticides to ensure that their use does not pose unreasonable risks to human health or the environment and that pesticide residues in food are safe. These determinations rely on and use the process of risk assessment. In assessing risk, the Agency considers all routes of exposure (e.g., dietary, incidental exposure in and around the home, etc.) and the inherent toxicity of the pesticide.

This user's guide will describe how OPP assesses dietary exposure from the foods that we eat and, more importantly, where in existing guidelines and other policy documents one can find more detailed, specific "how-to" information. The first section, "A Primer on Dietary Exposure and Risk," provides a very simple overview of dietary exposure and risk assessment. The next two sections are the "nuts and bolts" of this paper, describing where one can find Agency guidance, policy, and information on generating data for and conducting dietary exposure assessment.

I. A PRIMER ON DIETARY EXPOSURE AND RISK

The risk that is posed by a pesticide in food depends on the toxicity of the pesticide and the amount of pesticide to which a person is exposed. That is, to determine whether there is any risk - which can result from either short- or long-term exposure - one compares the inherent toxicity of the pesticide to the amount of pesticide to which an individual may be exposed. The toxicity is expressed as either an acute reference dose (aRfD) or a chronic reference dose (RfD), if the endpoint of toxicity is not cancer. The default assumption is that all non-cancer endpoints have a threshold, which means that an effect will not occur until a certain dose is reached. For cancer, toxicity may be expressed as a potency factor (q_1^*), when the cancer response is assumed to have no threshold or as a Margin of Exposure (MOE), when the cancer response is believed to have a threshold.

A. Toxicity

1. Non-Cancer Effects

a. *Acute Reference Dose*

An acute reference dose (aRfD) is an estimate of the level of one-day exposure to a pesticide residue that is believed to have no significant deleterious effects. It is calculated by first determining the No-Observed-Adverse-Effect Level (NOAEL) from acute toxicity (animal or human) studies and dividing it by the appropriate uncertainty factors – a 10-fold factor is applied to account for variation within the human population (i.e., intraspecies); and, if an animal study is used, a 10-fold factor is applied to account for the differences between humans and animals as the animal data are translated to humans (interspecies).

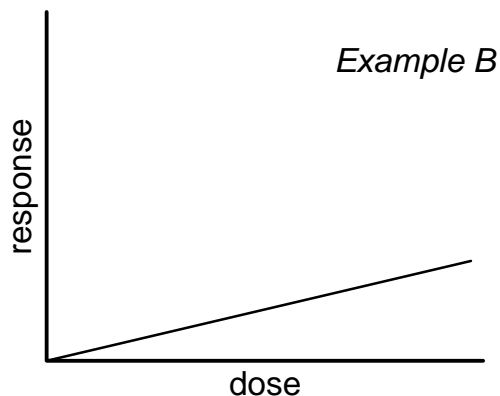
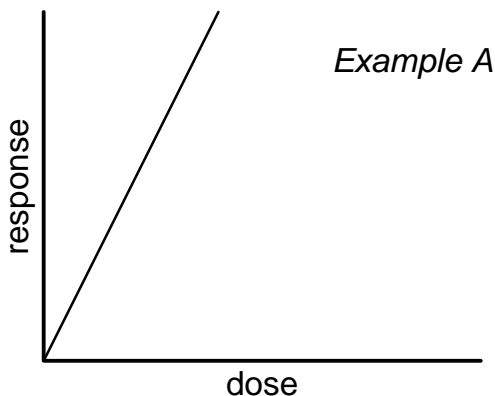
b. *Chronic Reference Dose*

A chronic reference dose is an estimate of the level of daily exposure to a pesticide residue, which, over a 70-year life span, is believed to have no significant harmful effects. The Food and Drug Administration refers to this as an acceptable daily intake or ADI. It is calculated the same way as is the aRfD, except the NOAEL is taken generally from chronic animal studies, although occasionally, human studies have been used.

3. Cancer Effects

a. *Non-threshold-Cancer Potency Factor (q_1^*)*

The cancer potency factor, which is commonly known as a q_1^* , is the relative strength of a carcinogen. Mathematically, it can be thought of as the slope of the dose-response curve:



The potency of the pesticide in Example A is greater than the potency of the pesticide in Example B. In reality, a q_1^* is a single number that is usually calculated from animal data using a computer model. The higher the number, the more potent the chemical as a carcinogen. For some non-pesticide carcinogens, human data have been used for this calculation.

b. Threshold effect-Margin of Exposure

For some carcinogenic pesticides, it is not considered appropriate to calculate a potency factor. In these cases, the cancer effect is assumed to have a threshold, as for non-cancer effects. In this case, a Margin of Exposure (MOE) is derived. The MOE is a ratio, calculated by dividing the toxicity Point of Departure (such as a NOAEL) by the estimated or calculated exposure level.

B. Dietary (Food) Exposure

Estimates of dietary exposure are derived from two distinct pieces of information: the amount of pesticide residue that is present in and on food (i.e., the residue level) and the types and amounts of food that people eat (i.e., food consumption). The residue information comes from the numerous crop field trials and other sources where the amount of pesticide residues on a given commodity is measured. Consumption information comes primarily from USDA surveys of what people eat. Both exposure and consumption are discussed further in their own sections, below.

C. Basic Equations

The basic equations used in calculating dietary risk are listed below. Please keep in mind that the actual dietary risk calculations are quite intensive and must be done using a sophisticated computer software program called DEEM (Dietary Exposure Evaluation Model), which estimates exposure based on the extensive data that are available in this area.

1. Acute Risk

Acute dietary risk is expressed as a percentage of the acute reference dose (%aRfD). If the calculated %aRfD is less than 100 (when aggregated with dietary risk from drinking water and non-dietary/non-occupational sources), the risk is generally considered to be acceptable if the acute RfD is based upon animal data.

$$\%aRfD = \frac{\text{Dietary Exposure (mg/kg/day)}}{aRfD} \times 100, \text{ where}$$

$$aRfD = \frac{NOAEL}{\text{Uncertainty Factors}}$$

2. Chronic Risk

Chronic dietary risk is expressed as a percentage of the chronic reference dose (RfD). If the calculated %RfD is less than 100 (when aggregated as described above), the risk is generally considered to be acceptable. The acute RfD is based upon animal data.

$$\%RfD = \frac{\text{Average Dietary Exposure (mg / kg / day)}}{RfD} \times 100, \text{ where}$$

$$RfD = \frac{NOAEL}{\text{Uncertainty Factors}}$$

3. Cancer Risk

a. Non-Threshold

Non-Threshold cancer risk is expressed as a probability and is commonly written as # x 10⁻⁶. For example, 1x10⁻⁶ means one chance in a million. It is calculated using the relationship:

$$\text{Cancer Risk} = \text{Average Dietary Exposure} \times q_1^*$$

The method used to calculate q_1^* is chosen so that actual cancer risks should nearly always (95% of the time) be lower than the calculated values. A calculated cancer risk of 1x10⁻⁶ means that a person receiving that lifetime exposure to the pesticide increases his or her risk of developing cancer by less than one chance in a million. That is, for every one million exposed persons, one would expect one more cancer than would otherwise occur).

b. Threshold

Threshold cancer risks are expressed as margins of exposure. The Agency has not yet reached agreement on how large an MOE must be in order to be considered acceptable. It is currently developing criteria by which to make that judgment.

II. THE AMOUNT OF PESTICIDE IN AND ON FOOD

Assessing the amount of pesticide that is in or on the foods that we eat – both for fresh, raw foods such as lettuce and processed foods such as frozen french fries – is a complex process that requires data from numerous sources along with an understanding of the duration of exposure (i.e., acute or chronic). Some of the data are required to be developed by pesticide companies so that they can be allowed to market or continue to market their products (see 40 CFR 158.240). Other data are obtained from state and federal monitoring programs, and others are voluntarily submitted by the *registrants* or obtained from other sources. Understanding the duration of exposure is significant because acute exposure is calculated differently from chronic exposure.

A. Data Sources

1. 40 CFR 158.240 Requirements

Under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA requires (under 40 CFR 158.240) registrants to submit a full battery of residue studies that provide the Agency with the data it needs (among other things) to: determine the nature of the residue (i.e., what are the metabolites? How is the pesticide broken down by the plant?) and amount of the residues in food. These data are used to set *tolerances* and in assessing dietary exposure and risk. Risk assessments using these tolerance-level data are often subsequently refined through the Agency's tiered approach, which is described later in this paper.

Data from the residue studies required under 40 CFR 158.240 are often referred to as “farm gate” residues. This means is that sampling occurs before the crop has entered the channels-of-trade and had a chance to “lose” any of its pesticide residues through any sort of processing such as washing. In addition to the residues being “farm-gate,” these data may be considered “worst-case” because the testing guidelines require that the pesticide under

Registrant. A company or person, usually the basic manufacturer, authorized to sell a particular pesticide product.

Tolerance. The maximum, legal limit of pesticide residue that is allowed to remain in or on a treated food commodity as it enters interstate commerce. Tolerances are enforceable limits.

Composite Sampling. Instead of analyzing for the residues on a single food item (e.g., an apple), the residue analysis is done on many individual items of food that have been thoroughly combined and blended.

The Limit of Detection (LOD). The minimum concentration that the analytical method can detect.

Limit of Quantitation (LOQ) is the minimum concentration which can be reliably and consistently quantified.

Pre-Harvest Interval (PHI). The interval between the last application of pesticide and harvest of the crop.

investigation be applied at the maximum application rate using the maximum number of applications and the minimum *pre-harvest interval*.

✓The Residue Chemistry Data Requirements May Be Found at:
40 CFR 158.240.

✓The Residue Chemistry Test Guidelines Are: Series 860 of the OPPTS
Harmonized Test Guidelines.

- Supplemental guidance on crop field trials (OPPTS
Guideline 860.1500) is available as HED SOP 98.2 (see,
U.S. EPA, 1998).

2. The USDA Pesticide Data Program

The Department of Agriculture's (USDA) Pesticide Data Program (PDP) is a joint USDA/EPA effort that was started in the early 1990's to measure pesticide residue levels in foods, including milk, that infants and children typically eat in larger proportions than adults. Ten states participate in the program: California, Colorado, Florida, Maryland, Michigan, New York, Ohio, Texas, Washington and Wisconsin. These states, plus others in their distribution network, represent more than half the nation's population, major agricultural states, and all regions of the country.

Over the past six years, 31 commodities have been included in PDP's sampling and testing profile. Each year, at least 12 different commodities, including milk, are included in the program. Samples are collected close to the point of consumption and are randomly selected to reflect marketplace availability. For fresh commodities, at least two years of pesticide residue data are collected and for processed products at least one year of data are collected.

In the laboratory PDP samples are prepared for testing by emulating consumer practices (e.g., washing and peeling) and are done as *composites*. For 1998, 8900 samples were scheduled for collection resulting in approximately 51,000 analyses. State and federal laboratories perform analyses for more than 100 pesticides using multi- and specific residue methods.

The PDP data are EPA's preferred monitoring data. The sampling protocol was developed in cooperation with the Agency and the data generated are designed to be used for the purpose of risk assessment. The *Limit of Detections* (LOD's) are low and there a significant number of samples are collected.

✓To Obtain More Information on the PDP Program or to Access

Summaries of the Data Contact USDA at:

<http://www.ams.usda.gov/science/pdp/index.htm>

✓ For More Information on how the Agency Uses the Data, Contact EPA:

Martha Lamont, Chemist

Health Effects Division

703-305-7335

lamont.martha@epamail.epa.gov

3. Food and Drug Administration Pesticide Monitoring Program Data

The Food and Drug Administration Pesticide monitoring program comprises three components: (1) regulatory monitoring, which includes both surveillance and compliance; (2) incidence/level monitoring; and (3) the Total Diet Study. EPA routinely uses the regulatory monitoring data and the Total Diet Study data in its dietary exposure assessments.

- ❖ **Regulatory Monitoring.** The regulatory monitoring component is directed toward enforcing tolerances in imported foods and in domestically produced foods shipped in interstate commerce. Under regulatory monitoring, FDA samples individual lots of domestically produced and imported foods and analyzes them for pesticide residues. Domestic shipments are collected as close as possible to the point of production in the distribution system; import samples are collected at the point of entry into U.S. commerce. Emphasis is on the raw agricultural product, which is analyzed as the unwashed, whole (unpeeled), raw commodity. Processed foods also are included.

Domestic and import food samples collected for analysis are classified as either "surveillance " or "compliance." Most samples collected by FDA are the surveillance type; that is, there is no prior knowledge or evidence that a specific food shipment contains illegal pesticide residues. Compliance samples are collected as follow-up to the finding of an illegal residue or when there is other evidence of a pesticide problem.

To analyze the large numbers of samples (which are collected and prepared as composites) whose pesticide treatment history is usually

unknown, analytical methods capable of simultaneously determining a number of pesticides are used. These multiresidue methods (MRMs) can determine about half of the approximately 400 pesticides with EPA tolerances, as well as many others that have no tolerances. The most commonly used MRMs can also detect many metabolites, impurities, and alteration products of pesticides with and without tolerances. Single residue methods (SRMs) or selective MRMs are used to determine pesticides not covered by an MRM. An SRM usually determines one pesticide; a selective MRM measures a relatively small number of chemically related pesticides.

- ❖ **Total Diet Study.** FDA uses the Total Diet Study to monitor a number of nutritional concerns, including pesticides. As part of the Total Diet Study, FDA staffers shop in supermarket or grocery stores four times a year, once in each of four geographical regions of the country. Shopping in three cities from each region, they buy the same 261 foods, including meat, selected from nationwide dietary survey data to typify the American diet. The purchased foods are called "market baskets."

Foods from the market baskets are then prepared as a consumer would prepare them. For example, beef and vegetable stew is made from the collected ingredients, using a standard recipe. The prepared foods are analyzed for pesticide residues, and the results, together with USDA consumption studies, are used to estimate the dietary intakes of pesticide residues for eight age-sex groups ranging from infants to senior citizens.

✓ For Further Information, Including Data Summaries from the Monitoring Programs, See:

<http://vm.cfsan.fda.gov/~dms/pesrpts.html>

4. State Monitoring.

A few states (e.g., California and Florida) collect their own pesticide monitoring data. When these are available, they may be used by EPA in dietary exposure assessments.

5. Special Studies

In addition to the studies required under 40 CFR 158.240, registrants and other interested groups such as grower groups, trade associations, food processors, etc. sometimes voluntarily submit additional data which are used for refining the risk

assessment. These “special data” include: market basket surveys and other studies that show how pesticide residues are reduced in the channels-of-trade and as the result of consumer practices such as washing and peeling.

6. The National Pesticide Residue Database (NPRD)

The NPRD is being developed as a comprehensive electronically-accessible database of quality pesticide residue food monitoring data collected in the United States. It includes many of the data mentioned above along with data from other sources. Specifically, NPRD includes data from: the FDA pesticide residue monitoring program, FDA Total Diet Study, USDA-AMS Pesticide Data Program, USDA-FSIS meat, poultry, and egg monitoring data, U. S. Department of the Interior Fish and Wildlife Service fish monitoring data, and state pesticide enforcement programs. It will also include monitoring data from Private monitoring sources such as the National Food Processors Association, as well as data collected by the pesticide chemical and food industries.

This database was created in response to the National Academy of Sciences' recommendation that all pesticide monitoring data be maintained in a standardized computer database (NAS, 1993). The NPRD will improve the representation of residues in the food supply by providing pesticide risk assessors with more samples, and will provide better data quality due to standardized reporting requirements. The public will have access to the data from federal and state monitoring programs. These public sources of data will be searchable on the Internet using standard queries.

EPA expects that this database will be online and available via the internet in the winter of 1999.

✓ For More Information on NPRD, Contact:

Sue Hummel, Chemist
U.S. EPA Office of Pesticide Programs
hummel.susan@epamail.epa.gov
703-305-7689

7. Percent Crop Treated

The Agency frequently uses information on how much of a crop is actually treated with a given pesticide in order to make as accurate an estimate of the residues as possible. EPA obtains this information from a variety of agricultural and non-agricultural data sources including the USDA National Agricultural Statistics Service (NASS), USDA National Agricultural Pesticide Impact Assessment Program (NAPIAP); various state surveys/census including California Department of Pesticide Regulation (DPR) census, as well as a variety of proprietary data sources. The data sources housed within EPA's Office of Pesticide Program contain pesticide information from all major crop producing states, selected crop information, international pesticide

usage, seed treatments, expert opinion for highly specialized uses, and registrant sales, marketing and client data. The non-agricultural pesticide usage data includes information on certified/commercial pesticide applicators, home and garden pesticide use, the pesticide use survey of the food processors, post harvest pesticide use, professional and consumer pesticide market information, global non-crop market pesticide data, biocide market information, and registrant sales, marketing and client data. The data sources, type of information gathered, frequency of data collection, type of data collection (e.g., survey, census, expert opinion) vary greatly. EPA economists analyze all available information and provide it to the risk assessors for use, when appropriate, in their dietary exposure estimates.

III. CONSUMPTION INFORMATION

Food consumption data are provided by USDA from their Continuing Survey of Food Intake by Individuals (CSFII). USDA has been conducting such food surveys since the 1930's by means of personal interviews in which interviewers ask individuals to recall everything they ate and drank over the previous 24 hours.

In the late 1970's, USDA conducted the National Food Consumption Survey, which was a large and comprehensive survey that sampled thousands of households to learn about what, and how much, people ate. EPA more recently has used them to develop its Dietary Risk Evaluation System (DRES), which is a computer model that combines the food consumption data with residue information to calculate the dietary exposure. Today, the newer DEEM model has replaced DRES. The consumption information used in DEEM has been significantly updated.

Over the course of 20 years, people's dietary habits have changed and the public health community has become more and more concerned with the unique susceptibilities of children's exposure to pesticides through their diets. As a result, EPA and USDA have been working to update the food consumption information. USDA has recently completed its 1994-96 CSFII. The data are available on CD-ROM. And, because of the increased emphasis on children's exposures to pesticides, USDA is now conducting a separate food consumption survey just for children. Data from this survey, which is called the Supplemental Children's Study, are expected in about two years.

For Further Information on USDA's Food Consumption Surveys, Contact:

✓TBA

IV. DATA COLLECTION AND RESIDUE ANALYSES

A. Quality Assurance: Good Laboratory Practices

It is critically important to the functioning of EPA's pesticide regulatory system that the Agency be able to trust the data on which decisions are based. Therefore, EPA has several active programs to assure that data submitted to the Agency in support of product registrations are reliable. First, EPA establishes detailed guidelines describing how studies must be performed (see also, section on "Data Sources"). In addition, each scientific study submitted to support registration for Agency review must have been conducted at a laboratory facility which follows the Good Laboratory Practices (GLP) regulations under 40 CFR 160.

The GLP Standards are a management tool to ensure that studies are conducted according to certain scientific standards. Each laboratory conforms with GLP requirements by implementing Standard Operating Procedures and maintaining quality assurance oversight through a Quality Assurance/Quality Control Unit which conducts internal audits of raw data and laboratory practices.

The mission of EPA's GLP program is to assure the quality and integrity of studies submitted to the Agency in support of pesticide product registration. EPA accomplishes this mission by conducting data audits to assure compliance with the GLP regulations. EPA conducts more than 300 study audits a year. These studies vary from chemical analysis of pesticides to long-term toxicity and carcinogenicity studies in mammals. Other audited studies may look at the effect of pesticides on the environment, residues of pesticides on commodities, and the efficacy of public health antimicrobial products.

Once the Agency receives data supporting registration data (e.g., residue chemistry, product chemistry, and if applicable, toxicology and environmental fate/effects), scientists from appropriate scientific disciplines thoroughly review the data. These reviews look not only at the substantive results, but also look for signs that the data may not be trustworthy, e.g., internal inconsistencies, discrepancies with tests run on similar products, or missing information on GLP compliance. If EPA has concerns regarding the submitted data, additional data may need to be requested, or the Agency may require that a laboratory audit be conducted.

✓ The Good Laboratory Practice Standards Are at: 40 CFR 160.

B. Residue Methods: Pesticide Analytical Manual (PAM)

For each new pesticide tolerance, the registrant must provide an analytical method that can be used for enforcement purposes. For an existing pesticide, analytical methods can be found in FDA's Pesticide Analytical Manual.

The Food and Drug Administration (FDA) is responsible under the Federal Food, Drug, and Cosmetic Act for enforcing tolerances established by EPA. In meeting this responsibility, FDA collects and analyzes food from commercial channels-of-trade. The Pesticide Analytical Manual (PAM) is published by FDA as a repository of the analytical methods used in FDA laboratories to examine food for pesticide residues for regulatory purposes. The manual is organized according to the scope of the analytical methods:

- ❖ **PAM Volume 1.** This contains MRMs that are used by FDA on a routine basis because of their efficiency and broad applicability, especially for analyzing foods of unknown pesticide treatment history.
- ❖ **PAM Volume 2.** This contains methods designed for the analysis of commodities for residues of only a single compound (although some methods are capable of determining several related compounds). These methods are most often used when the likely residue is known and/or when the residue of interest cannot be determined by common MRMs.

✓ PAM Volume 1: <http://vm.cfsan.fda.gov/~frf/pami1.html>

✓ PAM Volume 2: <http://vm.cfsan.fda.gov/~frf/pami1.html>

C. Limit of Detection and Limit of Quantification (LOD and LOQ)

In analyzing for pesticide residues in food (or other substances), quite often, no residues are seen above the “limit of detection.” That is, the instrumentation in the laboratory is not able to detect any residue below a specified level, which is called the “limit of detection” or LOD. A typical LOD would be 0.01 ppm. However, even though the laboratory instrumentation cannot detect a residue, a residue may be present, at some level below the LOD, and such residues would contribute to dietary exposure. Current EPA policy is to assume that non-detected residues remain on treated commodities at ½ the LOD or LOQ, depending on which is available. The LOQ is the lowest concentration that can be reliably and consistently quantified. This assumption sometimes leads to overestimates of exposure and risk. The Agency is in the midst of developing statistical methods for better handling of data sets that contain both detected and nondetected residues. Draft policy documents have been published in the *Federal Register* for public comment.

✓ Draft Policy Paper: "Assigning Values to Nondetected/Nonquantified Pesticide Residues in Human Health Dietary Exposure Assessments" (63 FR 67063).

✓ Draft Policy Paper: "A Statistical Method for Incorporating Nondetected Pesticide Residues into Human Health Dietary Exposure Assessments" (63 FR 67063).

V. CONDUCTING DIETARY (FOOD) EXPOSURE ASSESSMENT

Dietary exposure assessment currently falls into two exposure categories -- acute assessments and chronic assessments -- each of which is calculated slightly differently. In an acute dietary exposure assessment, the risk assessor is trying to estimate the magnitude of exposure that a person could encounter on a single day. The reason for estimating the daily exposure is that the assessor is trying to estimate exposure in situations where a person consumes food with higher than average pesticide residues.

In chronic exposure assessment, the risk assessor is trying to estimate an average person's exposure over a lifetime. Consequently, using average residue values is appropriate.

A. Tiering: General Approach to Assessing the Amount of Pesticide in or on Food

In determining the amount of pesticide residue in and on food, EPA uses what it refers to as a "tiered approach." This tiering is done by assessing dietary exposure (and in turn risk) by first assuming that all food contains pesticide residues at the tolerance-level, which EPA considers to be "worst-case." If the risks are unacceptable based on these "worst-case" residue levels, EPA then will "refine" them by incorporating more "real-world" information into the exposure assessment, such as the level of pesticide on foods as eaten. The principal reason that this tiered approach is resource efficiency, both for the Agency and for those who must generate the data. Depicted in the following chart are the four tiers of dietary exposure assessment currently employed, noting key data elements in each tier.

TIER	ASSESSMENT TYPE	
	ACUTE	CHRONIC
1	RESIDUES: Tolerance Level % CROP-TREATED: 100	RESIDUES: Tolerance Level % CROP-TREATED: 100
2	RESIDUES: <u>Single-serving items</u> <u>Blended Commodities</u> Tolerance level Average field trial (or HAFT*) % CROP-TREATED: 100	RESIDUES: Tolerance Level % CROP-TREATED: Actual
3	RESIDUES: <u>Single-serving items</u> <u>Blended Commodities</u> Distribution of crop- Average of crop field field residues residues OR distribution of monitoring data. % CROP-TREATED: Actual	RESIDUES: - Average residues from field trials and or monitoring data. - Incorporate processing factors - Refined livestock dietary burdens and MMPE residue values % CROP-TREATED: Actual
4	Market basket surveys (single serving sized samples) Cooking, residue decline, residue degradation, etc.	Special studies (market basket surveys, consumer processing studies, residue degradation studies, etc.)

*HAFT means Highest Average Field Trial.

✓ Policy on Tiering: Acute Dietary Exposure Assessment Office Policy (U.S. EPA, 1996).

B. Acute Exposure Assessment

As mentioned earlier, in assessing acute dietary exposure, the risk assessor is trying to estimate the exposure that a person could encounter on a particular day if he or she consumed a food or several foods with higher than average pesticide residues. Ideally, the way to do this would be to have pesticide residue data on individual pieces of fruits or vegetables. For a variety of reasons, this is generally not possible. Therefore, the risk assessor must simulate, using available data, what a single-day high exposure would be. Using the above tiering scheme, the risk assessor would start with tolerance level residue and 100 percent crop treated and continue to "refine" the data using more and more sophisticated and "real-world" information. The difference between the single-serving items (apples) and blended commodities (applesauce) has to do with trying to estimate what a single day of high exposure would be.

The Agency has recently started to receive from registrants probabilistic risk assessments for single-serving food items (e.g., apples but not applesauce). A probabilistic analysis uses the entire range of data from the numerous crop field trial studies, or other sources to estimate the distribution of exposure to the residues for the population of concern. This technique allows for a more realistic estimate of exposure. Last spring, the Agency brought before the FIFRA Scientific Advisory Panel (SAP) a draft policy and a series of guiding principles for the submission and use of probabilistic risk assessment techniques. On November 5, 1998, EPA announced in the *Federal Register* (63 FR 59780) the availability (for review and comment) of a draft science policy document entitled "Guidance for Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs." This document is designed to provide guidance for submission and review of probabilistic human health exposure assessments in the Agency's Office of Pesticide Programs (OPP).

✓ "Guidance for Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs;" draft document. 63 FR 59780.

C. Chronic Exposure Assessment

As mentioned earlier, in assessing chronic dietary exposure, the risk assessor is interested in estimating the level of exposure over a lifetime. Therefore, using average values for residues is appropriate for this task. Again, as in the acute exposure assessment, the risk assessor starts with tolerance level residues and 100 percent crop treated data and works down through the tiers, as needed. As seen in the chart, for chronic exposure assessment, there is no distinction between single-serving and blended foods.

"Guidelines for the Use of Anticipated Residues in Dietary Exposure Assessment." March 25, 1991

VI. BIBLIOGRAPHY

DOCUMENT	DESCRIPTION
Residue Chemistry Data Requirements. 40 CFR 158.240.	This is where the data requirements for residue chemistry are delineated.
Series 860 - Residue Chemistry Test Guidelines	Guidance for the registrants telling them how to conduct the required studies and information for reviewers who analyze the submitted information.
U.S. EPA, 1998. Memorandum from Margaret Stasikowski to Jim Jones, Anne Lindsay, and Lois Rossi. "Supplementary Guidance on use of OPPTS Residue Chemistry Test Guidelines 860.1500, Crop Field Trials (residue zone maps - Canadian extension). April 8, 1998	This memo, which is also known as HED SOP 98.2, lets reviewers know that it is now possible for studies conducted in Canada to support domestic food uses of pesticides and their associated tolerances.
U.S. EPA, 1991. Guidelines for the Use of Anticipated Residues in Dietary Exposure Assessment." March 25, 1991.	A guidance document that describes how the Agency calculates anticipated residues for chronic exposure assessment.
U.S. EPA, 1996. Memorandum from Debra Edward to Staff. "Final Office Policy for Performing Acute Dietary Exposure Assessment." June 13, 1996.	An SAP reviewed policy on how OPP performs acute dietary exposure assessments, using a tiered approach.
National Academy of Sciences, 1993. "Pesticides in the Diets of Infants and Children." National Academy Press, Wasington, DC.	